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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/253,973	06/03/94	MCBRIDE W	DITI109

HM12/0409

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EXAMINER	
HARTLEY, M	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/253,973	McBride et al.
Examiner	**Group Art Unit**
Hartley	1616

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11-16-98.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 2-8 and 10 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 2-8 and 10 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 32 (1 sheet) ☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other_____

Office Action Summary

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (USP 5,688,485) in view of Fritzberg (USP 5,091,514), for the reasons set forth in the office action mailed 7-24-98.

Applicant's arguments filed 11-16-98 have been fully considered but they are not persuasive.

Applicant asserts that the instant monoamine, diamide, single thiol-containing ligands differ from those disclosed by Harris, which are preferably diaminodithiol ligands.

This is not found persuasive because Harris discloses ligands having a formula which encompasses ligands having the donor set SNNN or NNNS (stereoisomeric forms) which may be monoamine, diamide, single thiol-containing ligands within the scope of the instantly claimed ligands. Although the preferred embodiments of the Harris invention may be diamine or diaminedithiol, there are no provisos set forth in the description of the formula which limit the formula to such compounds. Thus, the disclosure of Harris teaches monoamine, diamide thiol containing ligands. Disclosed examples and preferred embodiments do not constitute a teaching

which is away from a broader disclosure or nonpreferred embodiments. *In re Susi, 169* USPQ 423 (CCPA 1971) and *In re Gurley*, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Applicant asserts that the express diamine statement in Harris precludes an interpretation of monoamine ligands.

This is not found persuasive because the "diamine" limitation of Harris appears to describe the two nitrogens atoms found in the formula of the Harris invention as shown in column 3. However, Harris clearly teaches that various R groups may form an oxygen atom, which would change the amine to an amide. This is clear from the formula as shown. One of ordinary skill in the art would have recognized that the disclosure of Harris teaches all the ligands within the scope of the disclosed formula. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 10 USPQ2d 1843 (Fed. Cir. 1989).

Applicant further asserts that since Harris is directed toward radiopharmaceuticals for scintigraphic urography, which themselves, appear to target the kidney, there would have been no motivation to add a targeting agent to such ligands.

This is not found persuasive because it is very well known in the art that such chelating agents may be conjugated to a targeting agent to provide the advantage of increased targeting and/or specific targeting of other organs and tissues. Harris is concerned with targeting the kidneys. Although the ligands may distribute in the kidneys, one of ordinary skill in the art would have been motivated to conjugate a targeting ligand to such chelators to gain the advantages of,

1) further increasing the organ (kidney) specificity or 2) target other organs or tissues with said ligands, as taught by, *inter alia*, Fritzberg. One of ordinary skill in the art would have been motivated to further improve the biodistribution of the ligands disclosed by Harris by conjugating a targeting agent thereto, as is very well known in the art, as shown by Fritzberg.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The conjugation of a targeting agent to a ligand is well known in the art, only taking into account knowledge which was within the level of ordinary skill at the time of the invention, as shown by Fritzberg.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. § 103(a). Therefore, the rejection is adhered to.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Michael Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on Tuesdays through Fridays and on alternate Mondays from 7:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

M. Hartley

Date: 4-6-99

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616